DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2015

Codman & Shurtleff, Inc.
Ms. Hannah Foley
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K150319
Trade/Device Name: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: May 11, 2015
Received: May 13, 2015

Dear Ms. Foley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150319

Device Name
MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems

Indications for Use *(Describe)*

MICRUSFRAME, DELTAFILL, and DELTAXSFT Microcoil Delivery Systems are intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

The GALAXY G3 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The GALAXY G3 XSFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Submitter

Codman & Shurtleff, Inc.
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Tel: (305) 265-6810
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Contact Person: Hannah Foley
Date Prepared: June 9, 2015

II. Device

Table 2: Device	
Device Proprietary Name	MICRUSFRAME Microcoil Delivery System, DELTAFILL Microcoil Delivery System, DELTAXSFT Microcoil Delivery System, GALAXY G3 Microcoil Delivery System, GALAXY G3 XSFT Microcoil Delivery System
Common or Usual Name	Device, Neurovascular Embolization & Vascular, For Promoting Embolization
Classification Name	Device, Neurovascular Embolization, Class II, 21 CFR 882.5950 & Vascular, For Promoting Embolization, Class II 21 CFR 870.3300
Regulatory Classification	II
Product Codes	HCG, KRD

III. Predicate Device

The corresponding predicate and reference devices that are listed in **Table 3** below are applicable to the devices being bundled in this submission.

Table 3 : Prior 510(k) Clearance			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
Predicate Device			
Predicate Device K082739	10/17/2008	Micrus Microcoil Delivery System**	Micrus Endovascular Corporation*
Reference Devices			
Reference Device K083646	01/02/2009	Micrus Microcoil System DELTAPLUSH	Micrus Endovascular Corporation*
Reference Device K033813	04/04/2004	Micrus Modified Microcoil System, Cerecyte	Micrus Endovascular Corporation*
Reference Device K053160	12/07/2005	Micrus Modified Microcoil 18-System, “Cerecyte”	Micrus Endovascular Corporation*
Reference Device K062036	08/25/2006	Micrus Microcoil System “Presidio-18”	Micrus Endovascular Corporation*
Reference Device K072173	10/05/2007	Micrus Microcoil Delivery System	Micrus Endovascular Corporation*
Reference Device K080437	05/08/2008	Micrus Microcoil Delivery System	Micrus Endovascular Corporation*
Reference Device K073442	02/26/2008	Micrus Microcoil Delivery System	Micrus Endovascular Corporation*
Reference Device K120686	04/04/2012	ORBIT GALAXY G2 Microcoil Delivery System	Codman & Shurtleff, Inc.
Reference Device K120274	03/02/2012	DELTAMAXX 18 Microcoil System	Codman & Shurtleff, Inc.
Reference Device K142429	12/24/2014	CODMAN, DELTAMAXX, and ORBIT GALAXY G2 Microcoil Delivery Systems and Cables	Codman & Shurtleff, Inc
Reference Device K093973	05/26/2010	ORBIT GALAXY Detachable Coil System	Codman & Shurtleff, Inc.
Reference Device K132281	08/30/2013	REVIVE Peripheral Vascular (PV) Thrombectomy Device	Codman & Shurtleff, Inc.
Reference Device K140080	04/24/2014	ENVOY Distal Access (DA) Guiding Catheter	Codman & Shurtleff, Inc.
Reference Device K123377	11/30/2012	Target Detachable Coils	Stryker Neurovascular

*On 09/27/10, Micrus Endovascular Corporation was acquired by Johnson & Johnson and now operates as a wholly-owned subsidiary of Codman & Shurtleff, Inc within the Johnson & Johnson family of companies. Medos International SARL (Medos) will be the recognized legal manufacturer and Codman & Shurtleff, Inc. will be the subcontractor appointed by Medos.
**The predicate Device Positioning Unit 2-3 (DPU2-3) was cleared under this submission.

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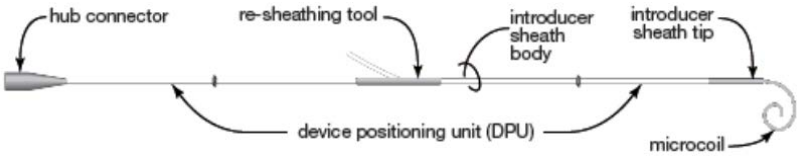
510(k) Summary, Continued

IV. Device Description

The MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems consist of three components, a Microcoil System, a connecting cable, and a Detachment Control Box (DCB). Each component is sold separately. As shown in **Figure 1**, the Microcoil System consists of a microcoil attached to a Device Positioning Unit (DPU).

Figure 1: Microcoil System



The Microcoil System is packaged in an introducer sheath designed to protect the coil in the packaging dispenser and to provide support for introducing the coil into the microcatheter catheter. The microcoil is the implantable segment of the device, and is detached from the Device Positioning Unit (DPU) using the Detachment Control System (Detachment Control Box and connecting cable).

- The microcoil is fabricated from a platinum alloy wire. The wire is wound into a primary coil which may contain either a polypropylene suture (SR) or an absorbable polymer suture and then formed into a secondary shape. The secondary shape may be spherical, complex, or helical.
- The DPU is a variable stiffness wire and has a radiopaque marker band located three (3) cm from its distal end. The Device Positioning Unit includes five (5) fluoro saver markers on the proximal section of the shaft. The markers are intended to indicate when the tip of the microcoil is approaching the tip of the microcatheter. When the distal-most marker reaches the proximal end of the Rotating Hemostatic Valve (RHV) on the microcatheter, the tip of the coil is approaching the tip of the microcatheter and fluoroscopy should be used to guide further coil insertion.
- The introducer sheath has three main components: an introducer tip, a translucent introducer body, and a re-sheathing tool.

The EnPOWER Detachment Control Box (DCB) provides the energy necessary to allow for a thermo-mechanical detachment of the microcoil from the DPU. The connecting cable delivers the energy necessary to detach the embolic coil from the Microcoil System's detachment zone. The connecting cable is connected between the Microcoil System's hub connector on the DPU and the output connector on the DCB.

- The connecting cables may be one of two types: one with a remote detach button (the EnPower Control Cable) catalog no. ECB000182-00, or one without a detach button (standard connecting cable) catalog no. CCB00157-00.
- The EnPower Detachment Control Box works with the EnPower Control Cable and with the standard connecting cable.

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510(k) Summary, Continued

IV. Device Description (Cont.)

The device in this submission includes design changes only to the Device Positioning Unit (DPU) element of the microcoil system. There are no modifications to the microcoil components or to the EnPOWER Detachment Control system. The following is a summarized list of the modifications to the predicate and reference devices:

- Minor design modifications to the Device Positioning Unit (DPU) to enhance the system's overall performance
- Labeling changes as a result of the minor design modifications and additional clarifications.
- Rebranding Microcoil Systems with new Proprietary Names (Refer to **Table 4)**

The currently cleared microcoils will be attached to the proposed Device Positioning Unit. The proposed microcoil system will remain compatible with the EnPOWER Control Box and Connecting Cables. These microcoil systems are also being rebranded with new proprietary names. **Table 4** provides a cross referenced summary of the currently cleared microcoils, secondary shape diameter and length, the 510(k) it was cleared under and new proprietary name with the proposed DPU.

Table 4: Microcoil Proprietary Name Conversion

Current Device Proprietary Names	Microcoil Secondary Shape Diameter and Length	510(k) Numbers	This Submission: Proposed Device Proprietary Names
MICRUSPHERE 10 & PRESIDIO 10 CERECYTE Coils	2mm-10mm x 1cm-30cm	K033813	MICRUSFRAME **S** 10 Stretch Resistant Coil
MICRUSPHERE 18 & PRESIDIO 18 CERECYTE Coils	2mm-20mm x 4cm-50cm	K062036 & K053160	MICRUSFRAME **S** 18 Stretch Resistant Coil
CASHMERE 14 CERECYTE Coil	2mm-12mm x 2.5cm-30cm	K072173	MICRUSFRAME **C** 14 Stretch Resistant Coil
DELTAPAQ 10 & DELTAPLUSH 10 CERECYTE Coils	1.5mm-10mm x 1cm-25cm	K080437 & K083646	DELTAXSFT 10 & DELTAFILL10 Stretch Resistant Coil
DELTAMAXX 18 CERECYTE Coil	3mm-24mm x 12cm-60cm	K120274	DELTAFILL 18 Stretch Resistant Coil
ORBIT GALAXY G2 FILL Stretch Resistant Coil	2mm-20mm x 1.5cm-30cm	K120686	GALAXY G3 Stretch Resistant Coil
ORBIT GALAXY G2 XSFT Stretch Resistant Coil	2mm-6mm x 1.5cm-8cm	K120686	GALAXY G3 XSFT Stretch Resistant Coil

S: Represents Spherical which is the Secondary Shape of the Microcoil.
C: Represents Complex which is the Secondary Shape of the Microcoil.

V. Indications for Use

MICRUSFRAME, DELTAFILL, and DELTAXSFT Microcoil Delivery Systems are intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

The GALAXY G3 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The GALAXY G3 XSFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

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510(k) Summary, Continued

VI. Comparison of Technological Characteristics With Predicate Device

Endovascular coil embolization is the technological principle for both the subject and predicate device. It is based on placing embolic coils in the neurovascular or peripheral vasculature in order to reduce or block blood flow. At a high level, the subject device and predicate device are based on the following same technological characteristics:

Table 5: Technological Characteristics of the Predicate and Proposed Devices

Description	Predicate Device: (K082739)	This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems
Indications for Use	The CODMAN Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature. The ORBIT GALAXY G2 FILL Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature. The XTRASOFT ORBIT GALAXY G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.	Same as predicate MICRUSFRAME, DELTAFILL, and DELTAXSFT Microcoil Delivery Systems are intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature. GALAXY G3 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.* The GALAXY G3 XSFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.*
Microcoil		
Microcoil Material	Platinum/Tungsten	Same as predicate
Microcoil Primary Wind	Triangular or Cylindrical	Same as predicate
Microcoil Secondary Shape	Complex, Helical, or Spherical	Same as predicate
Microcoil Stretch-Resistant	PGA= Polyglycolic Acid Suture PP= Polypropylene Suture	Same as predicate
Primary Coil Wind Outer Diameter (OD)	0.009" – 0.016"	Same as predicate
Secondary Shape OD Ranges	1.5mm – 24mm	Same as predicate
Microcoil Length Ranges	1cm - 60cm	Same as predicate
Delivery System		
Delivery System Type	Wire Shaft with radiopaque marker	Same as predicate
Delivery System Introducer Sheath	HDPE Introducer	Same as predicate
Delivery System Resheathing Tool	Nylon 12	Same as predicate
Device Positioning Unit (DPU) Delivery System Length	190cm ± 5cm	Same as predicate
Device Positioning Unit Diameter	0.0138"	**0.0159"**
Fluoroscopy Saver Markers	None	**Five Markers Located on the Proximal Section of the Shaft****
Fluoro Saver Marker Microcatheter Compatibility	Not Applicable	**150cm Length****
Distal Segment of the Device Positioning Unit	Device Positioning Unit 2-3 (DPU2-3)	**Device Positioning Unit 3 (DPU3) Design modified to enhance overall performance**
Mechanism of Detachment	Connection to Microcoil System: Uses Connecting Cable or EnPOWER Control Cable Detachment: Thermo-Mechanical System uses the EnPOWER Detachment Control Box (DCB) with EnPOWER Control Cable or Connecting Cable	Same as predicate
Sterilization and Shelf Life		
Sterilization Method	E-Beam Radiation	Same as predicate
Shelf Life	5 years	**18 months**
Packaging	Packaged in a plastic hoop and enclosed in a pouch.	Same as predicate

Note: Size ranges provided cover entire microcoil product offering.
*The GALAXY G3 Microcoils are the same Microcoils cleared under reference device K120686 ORBIT GALAXY G2 Fill and Xtrasoft Microcoils therefore the same indications for use were utilized.
** Same material and similar use as the REVIVE PV Peripheral Vascular Thrombectomy Device K132281.

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510(k) Summary, Continued

VII. Performance Data

Verification and Validation Testing

There were no changes made that affect the Microcoils intended use, operational principle, design principle, manufacturing or sterilization processes. The modifications proposed in this submission are for the Device Positioning Unit (DPU) only.

Verification and validation activities were focused on the Microcoil Systems' proposed Device Positioning Unit (DPU3). Appropriate testing was identified based on the modifications and a review of the products' risk analyses and previous use of the predicate Device Positioning Unit 2-3 (DPU2-3) which was cleared under K082739. Testing was conducted as appropriate for the inclusion of the proposed DPU based on current standards and FDA Guidance Document; "*Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices*"; all testing was performed on final sterile product unless otherwise justified. The following performance data were provided in support of the substantial equivalence determination. All testing was conducted using statistical sampling methods as required by the Codman & Shurtleff, Inc. Design Control procedures. The bench testing included the following tests:

Table 6: Verification and Validation Testing

Test	Test Method Summary	Results
Microcatheter Stability (Tip Deflection Force)	The purpose of the Microcatheter Stability (Tip Deflection Force) test is to measure the deflection and/or stability of the microcatheter by recording the force generated at the distal tip of the microcatheter as the DPU device is advanced to the tip of the microcatheter.	PASS: Samples passed the established acceptance criterion
Coil Detachment Durability & Reliability	The purpose of the Coil Detachment Durability & Reliability test was to evaluate the reliability of the detachment mechanism of the proposed device after being cycled into and then out of a clinically relevant anatomical model six times.	PASS: Samples passed the established acceptance criterion
Coil Durability (Coil to Device Positioning Unit)	The purpose of the Coil Durability test was to evaluate the coil's ability to stay attached to the proposed device during simulated use of six insertions and withdrawals cycled into and out of a clinically relevant aneurysm model.	PASS: Samples passed the established acceptance criterion
Distal Outer Sheath Durability	The purpose of the Distal Outer Sheath Durability test was to evaluate the durability of the distal outer sheath during the simulated use of six insertions and withdrawals of the proposed device into and then out of a clinically relevant aneurysm model.	PASS: Samples passed the established acceptance criterion
Track Force (Delivery)	The purpose of the Track Force test was to evaluate the force it takes to deliver the proposed device through a microcatheter and into a clinically relevant model; utilizing the system Catheter Performance Simulation System (CPSS).	PASS: Samples passed the established acceptance criterion
Re-Sheathing Reliability	The purpose of the Re-Sheathing Reliability test was to evaluate the ability to re-insert the proposed device into the split sheath introducer after it has been unzipped after the proposed device has been inserted and withdrawal from a clinically relevant model.	PASS: Samples passed the established acceptance criterion
Fluoro Saver Marker Durability	The purpose of the Fluoro Saver Marker Durability test was to evaluate the ability of the Fluoro Saver Markers ability to stay affixed and in the correct position on the shaft of the propose device after being cycled into and then out of a clinically relevant anatomical model six times.	PASS: Samples passed the established acceptance criterion
Detachment Zone Tensile Strength	The purpose of the Detachment Zone Tensile Strength test was to evaluate the attachment strength of the detachment fiber that holds the microcoil to the proposed device by measuring the force it takes to break the fiber.	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of the Outer Diameter	The purpose of the Dimensional Inspection of the Outer Diameter of the proposed device is to verify the OD is within specification to ensure microcatheter compatibility.	PASS: Samples passed the established acceptance criterion

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510(k) Summary, Continued

VII. Performance Data (Cont.)

Table 6: Verification and Validation Testing, Continued

Test	Test Method Summary	Results
Dimensional Inspection of Overall Length	The purpose of the Dimensional Inspection of the Overall (OAL) Length of the proposed device was to verify that the proposed device is of appropriate length to be compatible with other required device need to complete a procedure.	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of the Length from the Distal Tip to the Radiopaque Marker Band	The purpose of the Dimensional Inspection of the Length from the Distal Tip to the Radiopaque Marker Band was to verify that the proximal radiopaque marker band is appropriately placed to allow the alignment with the microcatheter's 3cm marker.	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of the Distal Fluoro Saver Markers	The purpose of the Dimensional Inspection of the Distal Fluoro Saver Marker was to verify that that the Fluoro Saver Markers are in the correct proximal position in order to give the physician a visual indication that the microcoil is approaching the distal tip of the microcatheter.	PASS: Samples passed the established acceptance criterion
Detachment Zone Microcatheter Surface Temperature Comparison	The purpose of the Detachment Zone Microcatheter Surface Temperature Comparison test was to compare the external surface temperature of the microcatheter distal tip during detachment of the proposed and predicate device.	PASS: The proposed device samples were found to have equivalent temperatures to the predicate device; which has established that the heat generated during detachment does not lead to an acute tissue inflammatory response.

Shelf-Life Testing

Shelf-Life Testing will be conducted on finished devices in accordance with FDA Guidance *Shelf Life of Medical Devices* issued April 1991 and internal requirements. Final sterile devices will be subjected to environmental conditioning, simulated transportation and accelerated and real time aging before being tested.

There were no modifications to the current packaging. The currently cleared packaging was validated in accordance with applicable recommendations in International Standard ISO 11607-1 "Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems" and ISO 11607-2 "Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes" as recognized by FDA.

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510(k) Summary, Continued

VII. Performance Data (Cont.)

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing Within a Risk Management Process", FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing.' May 1, 1995", and FDA's Draft Guidance Document (April 23, 2013) entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The following tests were performed:

Table 7: Biocompatibility

Test	Test Method	Results
In Vitro Cytotoxicity – ISO MEM Elution with serial dilutions (DPU3 wire cut into smaller segments)	ISO 10993-5: 2009 ISO 10993-12: 2012	PASS
In Vitro Cytotoxicity – ISO MEM Elution (uncut DPU3)	ISO 10993-5: 2009 ISO 10993-12: 2012	PASS
Guinea Pig Sensitization – ISO Maximization	ISO 10993-10: 2010 ISO 10993-12: 2012	PASS
Intracutaneous/Irritation Reactivity – ISO Skin Irritation Study in Rabbits	ISO 10993-10: 2010 ISO 10993-12: 2012	PASS
Acute Systemic Toxicity – ISO Systemic Toxicity in Mice	ISO 10993-11: 2006 ISO 10993-12: 2012	PASS
Material Mediated Pyrogenicity – USP Rabbit Pyrogen	ISO 10993-11: 2006 ISO 10993-12: 2012 USP 37, NF 32, 2014 General Chapter <151>, Pyrogen Test ISO 10993-12: 2012	PASS
Endotoxin – USP Limulus Amebocyte Lysate (LAL) Kinetic-Chromogenic Method	AAMI ST72: 2011 USP 37, NF 32, 2014 General Chapter <85>, Bacterial Endotoxins ISO 10993-12: 2012	PASS
In Vitro Ames Bacterial Reverse Mutation Assay	ISO 10993-3: 2014 ISO 10993-12: 2012 OECD 471: 1997	PASS
In Vitro Mouse Lymphoma Mutagenicity Assay	ISO 10993-3: 2014 ISO 10993-12: 2012 OECD 476: 1997 ASTM E1280: 2008	PASS
In Vivo Mouse Peripheral Blood Micronucleus Assay	ISO 10993-3: 2014 ISO 10993-12: 2012 OECD 474: 1997	PASS
In Vitro Hemolysis (ASTM Method – Direct Contact and Extract)	ISO 10993-4: 2002/(R)2013 ISO 10993-12: 2012 ASTM F756: 2013	PASS
ASTM Partial Thromboplastin Time	ISO 10993-4: 2002/(R)2013 ISO 10993-12: 2012 ASTM F2382: 2010	PASS
C3a Complement Activation	ISO 10993-4: 2002/Amendment 1 2006 ISO 10993-12: 2012	PASS
SC5b-9 Complement Activation	ISO 10993-4: 2002/Amendment 1 2006 ISO 10993-12: 2012	PASS
In Vivo Thromboresistance in Dogs	ISO 10993-4: 2002/(R)2013 ISO 10993-12: 2012	PASS
USP Physicochemical Tests (Aqueous Extracts)	USP 37, NF 32, 2014 General Chapter <231> Heavy Metals General Chapter <281> Residue on Ignition General Chapter <661> Containers-Plastics General Chapter <791> pH	PASS
Determination of Extractable Metals By Inductively Coupled Plasma - Optical Emission Spectroscopy (ICP-OES)	ISO 10993-18: 2009	PASS
Physicochemical Tests (Non-aqueous Extracts)	USP 37, NF 32, 2014 General Chapter <281> Residue on Ignition General Chapter <661> Containers-Plastics General Chapter <731> Loss on Drying General Chapter <851> Spectrophotometry and Light-Scattering	PASS

The Microcoil System is comprised of the microcoil and the Device Positioning Unit (DPU). The DPU is considered blood contacting for duration of less than 24 hours while the Microcoils are considered permanent implants. Because only the design of the Device Positioning Unit was modified, the biocompatibility testing was conducted on the Device Positioning Unit.

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510(k) Summary, Continued

VII. Performance Data (Cont.)

Sterilization

The Microcoil System is electron beam sterilized and was validated and audited to assure a Sterility Assurance Level (SAL) 10^{-6} according to the requirements of International Standards ISO 11137-1 "Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices", ISO 11137-2 "Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose", ISO 11137-3 "Sterilization of Health Care Products – Radiation – Part 3: Guidance on dosimetric aspects", and ISO 11737-1 "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products" as recognized by FDA

Animal Study

An animal study was not required as appropriate verification and validation of the modified Device Positioning Unit (DPU) was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Summary of Clinical Testing

A clinical study was not required as appropriate verification and validation of the modified Device Positioning Unit (DPU) was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

VIII. Conclusion

Based upon the design, materials, function, intended use, performance, manufacturing and sterilization process and the non-clinical testing performed by Codman, it is concluded that the MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 and GALAXY G3 XSFT Microcoil Systems with the modified Device Positioning Unit are substantially equivalent to the currently marketed CODMAN, DELTAMAXX, and ORBIT GALAXY G2 Microcoil Systems (K082739) and therefore, does not raise any new questions of safety or effectiveness.